SEP 1 1 2000

SECTION 10

510(k) SUMMARY K001784

This 510(k) summary of safety and effectiveness for the Viridis laser (frequency doubled Nd:YAG) is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: COSMOS Medical Technology, Inc.

Address: 42230 Zevo Drive
Temecula, CA 92590

Manufacturer: Quantel Medical
89 Bd Etienne Clemental
Clermont-Ferrand
France
(+33) 473 25 62 27
(+33) 473 25 54 11

Contact Person: Mr. John Clark

Telephone: 909-587-6306
909-587-6406 (Fax)

Preparation Date: (of the Summary) July 2000

Device Name: Viridis laser (frequency doubled Nd:YAG laser)

Common Name: Nd:YAG laser (frequency doubled Nd:YAG laser)

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810).
Product Code: GEX
Panel: 79

Predicate devices: The COSMOS Compact KTP laser.

Device description: The Viridis laser emits a beam of coherent light at 532 microns.

Indications: The Viridis laser is intended for photocoagulation of pigmented lesions in dermatology.

These include the following specific applications:

Benign Vascular Lesions
Port Wine Stains
Erythrosis
Couperosis
Facial Telangiectasias
Leg Veins - Micro varicosities
Benign Pigmented Lesions
Senile Lentigo

The examples are not intended to be exhaustive or complete but to serve as a general guide to surgeons.

COSMOS Medical Technology, Inc., proposes that the Viridis laser be labeled:

"CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

Performance Data: None required.

CONCLUSION: Based on the information in the notification COSMOS Medical Technology, Inc., believes that the Viridis frequency doubled Nd:YAG is substantially equivalent to the cited legally marketed predicate for the indications requested in the notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2000

Mr. John Clark
Chief Executive Officer
Cosmos Medical Technology, Inc.
42230 Zevo Drive
Temecula, California 92590

Re: K001784
Trade Name: Viridis Laser (frequency doubled Nd:YAG laser)
Regulatory Class: II
Product Code: GEX
Dated: June 10, 2000
Received: June 13, 2000

Dear Mr. Clark:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K001784

Device Name: Viridis Laser (frequency doubled Nd:YAG laser)

Indications for Use Statement:

The Viridis is intended for the coagulation, ablation, vaporization, incision, excision, and/or cutting of soft tissue in dermatology.

Examples of applications include:

Benign Vascular Lesions
Port Wine Stains
Erythrosis
Couperosis
Facial Telangiectasias
Leg Veins - Micro varicosities
Benign Pigmented Lesions
Senile Lentigo

The examples are not intended to be exhaustive or complete but to serve as a general guide to surgeons.

COSMOS Medical Technology, Inc., proposes that the Viridis laser be labeled:

"CAUTION: Federal (US) law restricts the use of this device to licensed professionals."

rev. 8/2000

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use ___
(Per 21 CFR 801.109)

Donna R. Bachner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001784